

### **REMARKS**

In this communication, Applicants have amended Claims 12, 14-16, 18 and 19, canceled Claims 13 and 17, and added new Claims 21-23. The amendments and the new claims are at least supported by the specification on pages 7-8 (immune cells), 21-22 (isolated cells) and 25-26 (autologous cells). No new matter is introduced. Claims 1-12, 14-16, and 18-23 are pending. Allowance of all pending claims is respectfully requested.

### **Specification**

The specification is objected to because of the disclosure of an amino acid sequence on page 22 without a respective sequence identifier. Applicants have amended the specification to include a sequence identifier for the amino acid sequence and provided a paper and computer readable form copy of the sequence listing. Withdrawal of the objection to the disclosure is respectfully requested.

### **Rejections under 35 U.S.C. § 101**

Claims 12-19 stand rejected under 35 U.S.C. § 101 for reasons stated on pages 4-5 of the Office Action. Specifically, the Examiner alleges that the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. Independent Claim 12 has been amended to recite “isolated cells,” which do not exist naturally and clearly indicate the hand of the inventor. This amendment is supported by the specification on page 21, lines 21 to page 22, line 8. Accordingly, the grounds of the § 101 rejection have been obviated and withdrawal of the § 101 rejection is respectfully requested.

### **Rejections under 35 U.S.C. § 112**

Claims 12-19 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner alleges that Applicants have not provided a sufficient written description of any structure, or species that is representative of the broad classes of cells or tumor antigen claimed. Applicants respectfully traverse the rejection.

The key to written description requirement, as elaborated by the Federal Circuit in Enzo Biochem, Inc. v. Gen-Probe Corp., is that the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. Enzo, 63 USPQ2d 1609, 1616 (Fed. Cir. 2002).

Independent Claim 12, as amended, is directed to a cellular composition for administration to a subject with cancer, comprising isolated cells incubated with an anti-MIF antibody and a tumor antigen. The term “cells” has a well-recognized meaning in the art and inherently defines the basic cellular structure. For example, the American Heritage Dictionary, 4<sup>th</sup> Edition, defines the term “cell,” when used in a biology field, as “the smallest structure unit of an organism that is capable of independent functioning, consisting of one or more nuclei, cytoplasm, and various organelles, all surrounded by a semipermeable membrane.” Similarly, the term “tumor antigen ” has been widely used in the art and generally refers to any cell-surface antigen of a tumor that does not occur on normal cells of the same origin (see e.g., Dorland’s Illustrated Medical Dictionary). Therefore, one skilled in the art would have no problem in recognizing the identity of the subject matter of the claim.

In addition, the terms “cells” and “tumor antigen” appeared in the original claims and are recited many times in the specification as filed (see e.g., page 8, line 22; page 7, line 16; page 8, line 13; and page 9, line 11). With regard to original claims, there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.

MPEP 2163, p. 2100-166. The absence of definitions or details for well-established terms or procedures should not be the basis of a rejection for lack of adequate written description. MPEP 2163, p. 2100-169. Accordingly, Applicants respectfully submit that Claims 12-19, as amended, are adequately supported by the specification. Withdrawal of the 35 U.S.C. § 112, first paragraph rejection for lack of written description is respectfully requested.

### **Rejections under 35 U.S.C. § 102**

Claims 12, 14, and 17-19 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Calandra et al. (hereinafter “Calandra”) for reasons stated on page 7 of the Office Action. Applicants respectfully traverse the rejection.

For anticipation under 35 U.S.C. § 102, the reference “must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.” (MPEP §706.02). “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. v. Union Oil Co. of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Independent Claim 12, as amended, is directed to a cellular composition for administration to a subject with cancer, comprising isolated cells incubated with an anti-MIF antibody and a tumor antigen.

Calandra generally describes a cellular composition comprising splenocytes incubated ex vivo with an anti-MIF antibody in the presence of staphylococcal toxic shock syndrome toxin 1 (TSST-1). TSST-1, however, is a bacterial toxin and but not a tumor antigen. Accordingly, Applicants respectfully submit that Calandra does not teach or suggest every element as set forth in Claim 12 and, therefore, does not anticipate Claim 12. Applicants further submit that Claims

14 and 17-19 are not anticipated by Calandra because they depend from Claim 12. Withdrawal of the 35 U.S.C. § 102(b) rejection is respectfully requested.


Claims 12, 14 and 17-19 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,645,493 to Bucala et al. (hereinafter "Bucala") for reasons stated on page 8 of the Office Action. Applicants respectfully traverse the rejection.

Bucala describes a cellular composition comprising splenic T-cells incubated ex vivo with an anti-MIF antibody. Bucala, however, does not teach a cellular composition comprising isolated cells incubated with an anti-MIF antibody **and a tumor antigen**. Accordingly, Applicant respectfully submit that Bucala does not teach or suggest every element as set forth in Claim 12 and, therefore, does not anticipate Claim 12. Applicants further submit that Claims 14 and 17-19 are not anticipated by Calandra because they depend from Claim 12. Withdrawal of the 35 U.S.C. § 102(b) rejection is respectfully requested.

In light of the above, Applicants submit that this application is now in condition for allowance and therefore request favorable consideration. If any issues remain which the Examiner feels may be resolved through a personal or telephone interview, the Examiner is respectfully requested to contact Applicants' counsel, Michael Ye at (202) 689-7212.

Respectfully submitted,

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